Appl. No.:   10/720,799
Filed: November 24, 2003
Applicant(s): Christopher J. Hanna, et al.
Title: Intelligent Medical Image Management System
Art Unit: 2624
Examiner: Liew, Alex Kok Soon
Docket No.:   901120.90011

DECLARATION OF TIMOTHY J. O'CONNOR
PURSUANT TO (37 CFR 1.132)

Dear Sir:

I, Timothy J. O'Connor, declare and say that:

1.   I am one of the inventors named on the above-identified application and I am currently employed as the Vice President of Product Development for TeraMedica, Inc. For approximately the last 7 years I have provided technical and business direction into the development of application software used for the long-term storage and management of medical images and associated clinical content. My current position requires that I maintain up-to-date knowledge on trends and techniques used in healthcare clinical information technologies, healthcare industry standards and practices, and healthcare software applications. I have spent much of my time at TeraMedica educating healthcare provider Chief Information Officers (CIO's) on the benefits of clinical information lifecycle management and the intelligent use of clinical metadata policies for the storage and management of large-volume medical image datasets. Prior to helping form TeraMedica, I spent ten years at the Mayo Clinic in Rochester Minnesota where I participated in a variety of clinical application projects. As part of Mayo's Clinical Informatics Laboratory and their Electronic Imaging Steering Committee, I was responsible for helping shape the clinical technology infrastructure.   During this period I acquired broad-based knowledge on enterprise clinical workflow and clinical information objects (including image and non-image objects).   I also led development or assisted in the development of a variety of healthcare software applications including Clinical HL7 Interface Engines, Radiology Information Systems (RIS), Picture Archiving and Communication Systems (PACS) and Tele-Radiology systems.   I have presented at several industry conferences including the Radiology Society of North America (RSNA) and the Society of Photographic Instrumentation Engineers (SPIE).

2.   My Educational background includes a Bachelors Degree in Computer Science and Mathematics from the University of Cincinnati, Cincinnati Ohio, and a Masters in Business Administration from Cardinal Stritch University, Milwaukee, Wisconsin.

3.   Conventional data management systems for the storage, retrieval and viewing of medical images (referred to in the field as picture archiving and communication systems, or "PACS"), typically have limited amounts of digital storage, a processor for storing and indexing images, and user workstations attached directly, or across a network, to the PACS for image display. These PACS are usually designed with a client-server structure. In such structures, the workstations, acting as image clients, run specific software designed for interacting with a specific PACS, acting as an image server, in order to obtain and display images. The specific server software on the PACS is designed to accept and respond only to the specific requests from the corresponding image-clients.

4.   PACS are satisfactory for use throughout a single clinical department (e.g., radiology, cardiology, neurology) in a hospital; however, they become insufficient when managing images from multiple imaging modalities, different clinical department, or throughout multiple hospitals in a large healthcare enterprise. A user needing access to images from multiple modalities on different PACS needs specific client software suited for each PACS image server, resulting in a burdensome and impractical means for managing medical images in an ever growing healthcare field.

5.   The storage of a large number of medical images, as well as any associated textual information (i.e., metadata) is clearly a complex and costly undertaking. Furthermore, consolidation in the health care industry has resulted in the formation of large, geographically widespread healthcare systems. These systems offer their patients high quality care and cost efficiency resulting from economies of scale. These healthcare systems achieve the full benefit of their economies of scale by providing an integrated network for the delivery of patient services. This means that specialized medical services, such as imaging services, are leveraged across all departments and all locations. This is not achieved with conventional image management systems, however, in which images are stored on department PACS at each location and images are archived by each department on film or tape.

6.   A complicating factor when managing medical images across an entire healthcare enterprise is that image storage policies are not uniform. Storage policies

may differ, for example, based on the imaging modality used (e.g., magnetic resonance imaging, computed tomography, ultrasound), the subject of the study (e.g., head, abdomen, heart), and the clinical department and hospital from which the image originates (e.g., radiology in hospital A, radiology in hospital B, cardiology in clinic C). The efficient management of medical images thus requires a system which stores images acquired from many different sources throughout a healthcare enterprise and stores the images on media and in a form that is most cost effective in accordance with specific policies associated with the healthcare enterprise. The system should also retrieve images from storage and deliver those images and their associated textual information to workstations throughout the healthcare enterprise, regardless of the particular standards or protocols that are used to acquire the images or information.

7.   The foregoing information is evidenced by the fact that several different PACS vendors exist in the healthcare field, resulting in many different "brands" of PACS that are incompatible with each other. This presents a significant problem for the expanding healthcare field in that the transfer of information between different PACS within the same healthcare institution or enterprise is excessively cumbersome. A healthcare institution cannot simply install a new PACS and expect instant data sharing with its existing systems. Instead, data must often be migrated by routing the images from old PACS into each new PACS such that the new PACS can create and maintain its proprietary indexing scheme. This data migration is typically a complex, time consuming process that often negatively impacts the new PACS clinical workflow during the migration period. In addition, this is an exceptionally expensive undertaking given that the typical storage capacity for a PACS is on the order of hundreds of terabytes and that the old PACS must be maintained throughout the migration process.

8.   The present invention is an image management system that receives images and their associated textual metadata from multiple different medical imaging systems and serves as a communication point between a plurality of different PACS and other healthcare data management systems. The image management system overcomes the drawbacks of previous medical image management systems by providing a business rules processor that, in accordance with a set of stored rules, evaluates the metadata associated with each image to intelligently decide where, and how, in a healthcare enterprise the image data should be stored. This provides one central image management system to oversee the flow of image data to a plurality of different PACS, each having different operating characteristics directly

incompatible with each other. Furthermore, it is important to note that not only does the metadata employed by the present invention contain textual information regarding the medical images, but also regarding the imaging systems that produced the images. By evaluating metadata indicative of an imaging device as well, better coordination of the transfer and retrieval of images throughout the healthcare enterprise network can be achieved.

9. It is important to note that the business rules processor is an adaptable system. That is, rules are not "hard-coded," but instead can be created and edited easily by a system operator. In this way, the image management system of the present invention can be modified to accommodate advances in medical technology or suit the needs of a specific clinical institution. For example, when a healthcare institute installs a new PACS, new management rules can be established to interact with this archiving system instead of requiring that the data contained on previous PACS be migrated to the new system. This not only saves time, but also reduces the computational burden on the healthcare enterprise.

10. A rule, as is defined in the present patent application, includes three parts. First, a rule includes a header that defines the name for the rule as well as its priority. Second, a rule includes a condition part that defines a condition or set of conditions that must be met in order for the rule to be evaluated as true. Third, a rule includes a reaction part that defines the action or set of actions that are to be executed when the condition part of the rule is evaluated as true. Consider the description of an exemplary rule employed by the present invention, which can be found in Table 3 of the patent application for the present invention:

> RULE: Edit image data and apply storage management rules based on clinical annotations of the diagnostic image. Large image data sets (full body CT, full motion video studies, etc.) may be archived to low cost, off line media for medical legal records, while segments of the image marked by the reviewing physician as significant to the diagnosis are selected for high availability working storage and clinical distribution.

11. Clearly, this rule will have a complex conditional structure that is dependent on several factors. From this example it should be further made evident that complex assessments are necessary for the efficient management of medical images in a healthcare enterprise. Not only does medical imaging data require vast amounts of data storage, and therefore expensive computational burden for transferring the data, but several different clinical departments (e.g., radiology, cardiology, neurology, general surgery, pediatrics) require access to medical images.

Moreover, different institutions and clinical departments within a healthcare enterprise may each have their own protocols and procedures, as evidenced by the a plurality of PACS that are incompatible for directly communicating with each other. Thus, the expanding healthcare field requires an easily adaptable system to optimize the management of images particular to the individual needs of a healthcare enterprise or institution. The present invention, therefore, provides an image management system that meets these needs of the clinical community by providing an image management system that can intelligently and automatically manage the storage and retrieval of medical images and associated clinical data.

12. I have reviewed the <u>Fuchs</u> patent (U.S. Patent No. 6,418,475) and find that is does not disclose the present invention. Instead, <u>Fuchs</u> discloses a local memory storage system for a medical imaging system. That is to say, <u>Fuchs</u> does not describe an image management system that receives medical image data from multiple imaging systems because it describes instead **_one_** medical imaging system having a local memory storage connected to the imaging system through a local network. Despite being connected to a local network, however, the storage of image data remains local to the particular imaging system and cannot be shared between medical imaging systems, clinical departments, or hospitals.

13. In <u>Fuchs</u>, images are relocated to external systems (e.g., client workstations and diagnostic consoles) based on patient data. This is commonly referred to as "routing" or "autoforwarding" of image data to external systems. <u>Fuchs</u> further states that this relocation is performed regardless of where the image data are stored. It is clear, then, that there is no business rules processor used by <u>Fuchs</u> to coordinate the transfer or management of images based on a set of stored rules and metadata. Instead, a user simply retrieves images corresponding to a particular patient at a workstation in order to view the images. The primary achievement of <u>Fuchs</u> is to disclose a system containing memory subsystems that operate in a manner such that the retrieval of images from these memory systems is stream-lined in order to minimize the load associated with transferring the requested data.

14. I have reviewed the <u>Morris</u> patent (U.S. Patent No. 5,058,185) and find that it does not disclose the present invention. Instead, <u>Morris</u> discloses an object management and delivery system for images of scanned documents. The object management system disclosed in <u>Morris</u> stores each object (i.e., image of a scanned document) to one of two storage devices depending on whether the image has a high or low resolution. In fact, _each_ document scanned has a high resolution, with a

low resolution copy automatically produced later. To increase the efficiency of retrieving an image, the "rules" taught by Morris simply state that if a low resolution copy is desired, that the object management system should look on the low resolution storage device. There is no concept of a business rules processor in this management chain.

15. Furthermore, Morris teaches that each image is assigned a permanent name. Contained within this name is information related to the date each image was created. Based on this information images are transferred from the high resolution storage device to a permanent optical storage device after a period of, for example, thirty days, in order to maintain adequate storage capacity.

16. Again, Morris is limited to teaching that an image is necessarily created at a given, high resolution. Subsequently, that image is compressed into a lower resolution copy for reduced storage size and both a high resolution and low resolution image are stored in respective storage devices. There is no business rules processor or equivalent system to intelligently manage the flow of data, nor is there any evaluation made in accordance with a set of stored rules to manage the transfer of data. Instead, every image that has a low resolution is sent to one storage device, and every image that has high resolution is sent to a different storage device. Furthermore, after a set period of time, images from the high resolution storage device are transferred to permanent storage. Every image produced by the object management system of Morris is stored in a predetermined manner that is hard-coded into the management system. This is a simple data management scheme that is wholly insufficient for the efficient management of medical images across multiple clinical departments or different healthcare institutions.

17. I have reviewed the Jamroga patent (U.S. Patent No. 6,574,742) and find that it does not disclose the present invention. While Jamroga discloses a system for managing the storage of medical images across a healthcare enterprise, it does not describe a business rules processor that evaluates metadata in accordance with a set of stored rules in order to determine how medical images are to be managed and stored across the healthcare enterprise. Instead, images are *always* transferred to both short- and long-term storage regardless of any information related to the images or where they were produced.

18. The Examiner has asserted that the presently claimed invention is viewed as obvious over the Fuchs and Morris patent; however, I respectfully

disagree with this assertion. The commercial success of our company, TeraMedica, has hinged on the very technology present in the ***claimed*** invention. If the present invention was, in fact, obvious to those skilled in the art, then our business would never have been able to move out from underneath the shadows of the healthcare industry leaders such as GE Healthcare and Siemens Medical Solutions. We are rapidly growing, and attracting reputable clientele. For example, our customers include:

- **The Mayo Clinic** - *Rochester, Minnesota*

Mayo Clinic is the first and largest integrated, not-for-profit group practice in the world. Doctors from every medical specialty work together to care for patients, joined by common systems and a philosophy of "the needs of the patient come first." More than 3,300 physicians, scientists and researchers and 46,000 allied health staff work at Mayo Clinic, which has sites in Rochester, Minn., Jacksonville, Fla., and Scottsdale/Phoenix, Ariz. Collectively, the three locations treat more than half a million people each year. The exceptional quality of care provided by the Mayo Clinic in Rochester, Minn., has been recognized in U.S. News & World Report's ranking of American hospitals for 18 consecutive years.

- **Johns Hopkins Hospital** - *Baltimore, Maryland*

The Johns Hopkins Hospital is a teaching hospital in Baltimore, Maryland, and is widely regarded as one of the world's greatest hospitals. Johns Hopkins Hospital has topped U.S. News & World Report's ranking of American hospitals for 17 consecutive years.

- **Marshfield Clinic** - *Marshfield, Wisconsin*

Founded in 1916, Marshfield Clinic is one of only a few large independent nonprofit medical clinics in the United States. Marshfield Clinic is comprised of 766 physicians in 80 medical specialties and subspecialties located in over 40 centers throughout northern, central, and western Wisconsin. Although Marshfield Clinic has become synonymous with the city of Marshfield, the Clinic's "community" goes well beyond the immediate area, embracing nearly all of Wisconsin and much of Michigan's Upper Peninsula.

An integral part of health care delivery at Marshfield Clinic is the Outreach Services program. Currently, there are over 1,200 hospitals, clinics, and other sites participating in a variety of outreach programs originating from the Clinic. Examples of the services provided include off-site physician consultation (involving 45 specialties), a 24-hour EKG interpretation via computer, mobile echocardiography, reference laboratory, regional blood banking, radiology, EEGs, orthotics/prosthetics, radiation physics, pulmonary function, and bio-medical electronics.

• Meriter Hospital - *Madison, Wisconsin*

Meriter Hospital is a 448-bed non-profit community hospital that provides comprehensive health services for residents of southern Wisconsin and areas of northwest Illinois. It is a major teaching affiliate of the University of Wisconsin, and the fifth largest hospital in Wisconsin. Meriter Hospital has been recognized at Mastery level by the Wisconsin Forward Award in both 2004 and 2005, and with a Governor's Award of Excellence in 2006. Meriter is proud to provide southern Wisconsin with innovative and comprehensive health care services. Meriter employs approximately 3,400 people, who are all expected to follow Meriter's Code of Ethics & Standards of Conduct. As a locally governed organization, Meriter is strongly committed to the people and communities it serves.

• Aurora Healthcare - *Milwaukee, Wisconsin*

Aurora Health Care is a not-for-profit health care system located in eastern Wisconsin and headquartered in Milwaukee. The system includes 13 hospitals, over 100 clinics, and more than 140 community pharmacies. With 25,087 employees including 3,385 physicians, Aurora is Wisconsin's largest private-sector employer.

• ProHealth Care - *Wisconsin*

Established in January 1998 as a non-stock, not-for-profit corporation, ProHealth Care includes Waukesha Memorial and Oconomowoc Memorial hospitals, 13 primary care clinics, home health care services, long-term care, a health and fitness center, and more. Services are continually being developed and added. Specialized tertiary services include advanced cancer care, cardiology (including open heart surgery), and the most active obstetrical/neonatal intensive care program in the county.

• Thedacare - *Wisconsin*

The third largest health care employer in Wisconsin and the largest employer in the state's second largest economic market, Northeast Wisconsin, with nearly 5,300 employees. Through a nearly 100-year history, ThedaCare has woven itself into the very fabric of the communities it serves.

• MD Anderson Cancer Center - *Houston, Texas*

The University of Texas M. D. Anderson Cancer Center is located in Houston on the sprawling campus of the Texas Medical Center. It is one of the world's most respected centers devoted exclusively to cancer patient care, research, education, and prevention. M. D. Anderson Cancer Center was created by the Texas Legislature in 1941 as a component of The University of Texas System, and the faculty numbers 1,272 (M.D. and Ph.D.). M. D. Anderson is one of the nation's original three Comprehensive Cancer

Centers designated by the National Cancer Act of 1971 and is one of 39 Comprehensive Cancer Centers today.

• **UC Davis Health System** - *Davis, California*

As the region's only academic medical center, UC Davis Health System is charged with discovering and sharing knowledge and providing the highest quality care to its community. Through its entities — UC Davis Medical Center, UC Davis School of Medicine, and UC Davis Medical Group — the health system works to advance health both in its local community and around the globe. Their patient care, diagnostic and specialized treatment programs, and bench-to-bedside research have earned national and international distinction. Further, their depth of expertise and resources, including the most advanced medical technology, has enabled UC Davis to be one of <u>U.S. News & World Report</u>'s best hospitals for 14 years and best medical schools for nearly a decade.

19.   The commercial success of TeraMedica, and its ability to attract, as customers, the high quality healthcare institutions listed above, has relied on the intelligent image management system offered under the trade name of Evercore®. This product is the direct commercial embodiment of the claimed invention. The Evercore® technology employs the business rules processor of the claimed invention, which is an important aspect of our marketing campaign. This is evidenced in the enclosed marketing brochure entitled, "TeraMedica Healthcare Technology: Statement of Unique Functionality" (herein referred to as <u>the statement</u>) that describes our Evercore® product (<u>The Statement</u>; page 1, in which the management rules are identified; page 3, in which the Chief Information Officer is able to inherently edit prior and create new management rules in the face of a changing healthcare institution; page 4, in which the intelligent management is provided through clinical policies, or rules; page 4, in which the clinical policies are decided from metadata). The direct marketing of the claimed invention is further evidenced in the enclosed product publication entitled, " Need an Archive? But Want More Than Images?: Evercore™ Clinical Information Manager Solution Overview" (herein referred to as <u>the overview</u>), which further describes our Evercore® product (<u>The Overview</u>; page 1, in which the use of rules in the management of medical images is mentioned; pages 14-17, in which different Storage Policies, or rules, are presented and defined).

20.   Regarding the Mayo Clinic in Rochester, Minn., for the better part of the 1990s, the Mayo Clinic studied the problem of image management across its entire healthcare system. Coupled with the rapid expansion of medical imaging
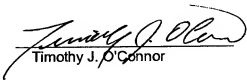
technology, the use of medical images in routine patient care was exponentially increasing. Noticing the need for technology that would be able to handle this rapid increase in the presence of medical images in routine care, the Mayo Clinic was determined to ensure that they could accommodate this expanding technology.

21.   The challenge was to develop an image management system and corresponding archive that could handle the vast size of The Mayo Clinic's healthcare system, which is one of the largest in the country. Furthermore, the image management system needed the ability to make an image available for viewing wherever, and whenever, it was needed. The Mayo Clinic sought out proposals for such an image management system in the late 1990s; however, all they received were bids to install a network including existing PACS technology. None of the industry leaders, such as GE Healthcare and Siemens Medical, were able to provide a solution that satisfied the requirements of The Mayo Clinic, which has around 1,200 employees in their Radiology Department alone, and performs over one million patient exams every year.

22.   This lack of technology lead the Mayo Clinic to build their own system. Chris Hanna, who is a co-inventor of the present invention, and I developed this technology, which we ended up commercializing through our start-up company, TeraMedica. If the combination of Fuchs and Morris would have lead those skilled in the art to the present invention, then the Mayo Clinic would certainly have had their solution from Siemens, who owns the Fuchs technology, on which the corresponding patent was filed in 1996.

23.   I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to me to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: _6/4/2008_____   _____
                                   Timothy J. O'Connor